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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): KULDEBRAND et al. Group Art Unit: 1616
Serial No.: 10/807,827 Examiner: David Paul Stitzel, Esq.
Filed: March 24, 2004 Docket No.: 134.02480101 (P-20905.00)
Confirmation No.: 4308
Title: INTRATHECAL GABAPENTIN FOR TREATMENT OF EPILEPSY

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):


- ☒ An itemized return postcard.
- ☐ A Petition for Extension of Time for __ month(s) and a check in the amount of \$__ for the required fee.
- ☒ An Information Disclosure Statement (2 pgs); copy of International Search Report (5 pgs); 1449 forms (4 pgs); and copies of 42 documents cited on the 1449 forms.
- ☐ A request for continued examination (RCE) and a check in the amount of \$, for the required filing fee.
- ☐ An Appeal Brief and a check in the amount of \$, for the required Appeal Brief filing fee.
- ☐ A check in the amount of \$__, for __.
- ☐ A certified copy of a __ application, Serial No. __, filed ____, the right of priority of which is claimed under 35 U.S.C. §119.
- ☐ Other:
- ☐ Amendment ☐ No Additional fee is required. ☐ The fee has been calculated as shown:

| Fee Calculation for Claims Pending After Amendment | | | | | |
|---|------------------------------------|-----------------------------|-----------------------------------|---------------------------|--------------------------|
| | Pending Claims after Amendment (1) | Claims Paid for Earlier (2) | Number of Additional Claims (1-2) | Cost per Additional Claim | Additional Fees Required |
| Total Claims | | | | x \$50 = | |
| Independent Claims | | | | x \$200 = | |
| One or More New Multiple Dependent Claims Presented? If Yes, Add \$360 Here → | | | | | |
| Total Additional Claim Fees Required | | | | | |

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 24th day of January, 2006.

MUETING, RAASCH & GEBHARDT, P.A.
Customer Number: 26813

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Kevin W. Raasch
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Direct Dial: 612-305-1218
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PATENT
Docket No. 134.02480101 (P-20905.00)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): HILDEBRAND et al.) Group Art Unit: 1616
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Confirmation No.: 4308) Examiner: David Paul Stitzel, Esq.
Filed: March 24, 2004)
For: INTRATHECAL GABAPENTIN FOR TREATMENT OF EPILEPSY)

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Also enclosed is a copy of an International Search Report from related foreign application PCT/US2004/034676. Per M.P.E.P. §609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 forms is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicant further requests that a copy of the 1449 forms, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Since this Information Disclosure Statement is submitted after the receipt of an Office Action in the above-identified patent application, please charge the fee of \$180 under 37 C.F.R. §§1.97(c) and 1.17(p), or charge any additional fees, or credit any overpayment, to Deposit Account No. 13-4895.

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Information Disclosure Statement

Page 2 of 2

Applicant(s): HILDEBRAND et al.

Serial No.: 10/807,827

Confirmation No.: 4308


Filed: March 24, 2004

For: INTRATHECAL GABAPENTIN FOR TREATMENT OF EPILEPSY

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number if they can be of any assistance during prosecution of the present application.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 24th day of January, 2006.


Kevin W. Raasch

January 24, 2006
Date

KWR/skd

Respectfully submitted

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| | Application Filing Date: March 24, 2004 | Group: 1616 |
| | Information Disclosure Statement mailed: January 24, 2006 | |

U.S. PATENT DOCUMENTS

| Examiner Initial | Document Number | Date | Name | Class | Subclass | Filing Date If Appropriate |
|------------------|-----------------|----------|----------------|-------|----------|----------------------------|
| | 5,713,923 | 02/03/98 | Ward et al. | | | |
| | 6,329,429 B1 | 12/11/01 | Schrier et al. | | | |
| | 2003/0195358 A1 | 10/16/03 | Montanari | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initial | Copy Enclosed | Document Number | Date | Country | Class | Subclass | Translation | |
|------------------|---------------|----------------------|----------|-------------------------------------|-------|----------|-------------|----|
| | | | | | | | Yes | No |
| | ✓ | DE 100 48 716 A1 | 04/18/02 | DE (English language abstract only) | | | | X |
| | ✓ | WO 03/068049 A2 & A3 | 08/21/03 | PCT | | | | |
| | ✓ | WO 03/061656 A1 | 07/31/03 | PCT | | | | |

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

| Examiner Initial | Copy Enclosed | Document Description |
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| | ✓ | Ben-Menachem et al., "Selected CSF biochemistry and gabapentin concentrations in the CSF and plasma in patients with partial seizures after a single oral dose of gabapentin," <i>Epilepsy Res.</i> , 1992; 11(1):45-49. |
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| EXAMINER | Date Considered |
| *Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

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| | ✓ | Cho et al., "The Effect of Intrathecal Gabapentin on Mechanical and Thermal Hyperalgesia in Neuropathic Rats Induced by Spinal Nerve Ligation," <i>J. Korean Med. Sci.</i> , 2002; 17:225-229. |
| | ✓ | "Clinical Trials: Brain Infusion of Muscimol to Treat Epilepsy," [online]. [retrieved on 2003-12-15]. Retrieved from the Internet:<URL: http://www.clinicaltrials.gov/ct/show/NCT00005925?order=1 >; 4 pgs. |
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| | ✓ | Kaneko et al., "Intrathecaly Administered Gabapentin Inhibits Formalin-Evoked Nociception and the Expression of Fos-Like Immunoreactivity in the Spinal Cord of the Rat," <i>J. Pharmacol., Exp. Ther.</i> , 2000; 292(2):743-751. |
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| | ✓ | Serpell et al., "Gabapentin in neuropathic pain syndromes: a randomised, double-blind, placebo-controlled trial," <i>Pain</i> , 2002; 99(3):557-566. |
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